

SUBMISSION TO:

**The Australian Government
Department of Health and Ageing**

**REVIEW OF FUNDING ARRANGEMENTS
FOR CHEMOTHERAPY SERVICES**



SUBMISSION BY:

**SYDNEY ADVENTIST HOSPITAL PHARMACY
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BACKGROUND

The Sydney Adventist Hospital is grateful for the opportunity to present a submission to the Review of Funding Arrangements for Chemotherapy Services.

The Sydney Adventist Hospital (SAH) is a division of Adventist HealthCare Limited and the largest single campus private not for profit hospital in NSW providing acute care services across the Hospital to over 210,000 inpatients and outpatients per year. The Hospital started in 1903 as a 70 bed 'Sanitarium' - a home of health and healing where people learned to stay well. Today it has over 500 beds, 2,200 staff, 800 visiting medical officers, and services patients in the fast growing North and North West region of Sydney.

The San Day Infusion Centre (SDIC) is the on-site infusion centre with 11 patient treatment chairs, and delivers over 8,000 oncology/chemotherapy infusions to approximately 5,000 patients each year. SDIC is also contracted by the Hornsby Ku-ring-gai Public Hospital to provide chemotherapy infusions to 100% of its public patients. This equates to over 40 patients per month and over 450 treatments per year.

Cancer related data for 2012 shows extensive patient usage. SAH had 11,893 separate admissions for cancer related episodes of care including:

- 5,166 patient admissions for over 8,000 chemotherapy infusions for more than 730 patients at the San Day Infusion Centre.
- 3,159 plus patient admissions to the Poon Oncology Ward specifically for medical (pharmacological) cancer treatment.
- 2,617 plus patient admissions for surgical cancer treatment.
- 873 cancer patient case studies benefit from group discussion at multidisciplinary cancer specialists meetings.

The need for our services will only increase in the future. This is evidenced by statistics that the Northern Sydney Central Coast Area Health Service has the greatest number of aged people of all the areas in NSW. It also has the greatest numbers of 'old old' (85+). The 75+ aged population was expected to increase by 10.8% in Northern Sydney (2001-2011) while the 85+ age group was projected to increase by 39%.

A 29% increase in cancer cases is expected in the Northern Sydney region between 2006 and 2021. Forward planning data commissioned by SAH estimates the increase in demand for our chemotherapy and medical oncology services from 2010-11 to 2016-17 could be 17.2% and 20% respectively.

In terms of the number of chemotherapy infusions supplied by the pharmacy oncology team, usage has increased by 74% in the 3-year period from 2010 to 2013. This has been due to the local acquisition of Sydney Haematology and Oncology Unit at Hornsby and the increase in chair capacity at the Day Infusion Centre.

Year	Number of Chemotherapy Infusions
2010-2011	5,000
2011-2012	8,000
2012-2013	8,700

TERMS OF REFERENCE 1 AND 2: HOW CHEMOTHERAPY MEDICINE INFUSIONS ARE PROVIDED, THE ROLE OF EACH SECTOR, AND HOW SERVICES AND FUNDING ROLES HAVE CHANGED OVER TIME.

1. Describe the model of care for the provision of chemotherapy medicine infusions that apply in your healthcare sector or the institution in which you practice. Please consider all components from the clinical decision to order an infusion to follow-up after the course or cycle has been completed.

Sydney Adventist Hospital Pharmacy operates a Section 90 licenced pharmacy, based on site, which delivers a full range of inpatient and community pharmacy services. This includes a comprehensive clinical service to inpatients in the Oncology ward and to day patients being treated at the 11-chair San Day Infusion Centre (DIC). Chemotherapy infusions for the DIC are sourced externally from a leading and nationally recognised specialised chemotherapy compounder.

The pharmacy chemotherapy services provided by Sydney Adventist Hospital Pharmacy are delivered through a dedicated in-house advanced care pharmacy team, comprised of a 3.5 FTE skills mix of specialised oncology pharmacists and a support technician. Their practice adheres to Society of Hospital Pharmacists of Australia (SHPA) *Standards of Practice for the Provision of Clinical Oncology Pharmacy Services* and the Clinical Oncology Society of Australia (COSA) *Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy*, albeit tailored to the operating requirements of SAH. This team is further supported by the Pharmacy Managers maintaining the departmental clinical, IT, procedural and risk management systems underpinning the pharmacy oncology infrastructure.

The main cancer states encountered by oncology pharmacists are: bowel (colorectal), breast, Non Hodgkins Lymphoma, prostate, multiple myeloma, ovarian and myelodysplastic syndrome. Contemporary cancer treatment involves the delivery of complex protocols of multiple chemotherapy medicines administered both sequentially and in parallel, together with standard treatments. It is recognised that management of these disease states with their complex dosing regimens and associated pharmacy skills require specialist oncology knowledge and it is imperative that their training and clinical oncology knowledge and skills are up to date. Also due to the complex nature of cancer medicines, accuracy, process and patient and staff safety are paramount.

Main Components in The Supply of a Patient's Chemotherapy Medication (infusion and associated medicines)

The basis for the role of the oncology pharmacist in the treatment of cancer is centred on the safe, accurate and appropriate provision of chemotherapy medicines and is required for every cycle of chemotherapy. The following activities form the main components performed by an oncology pharmacist at SAH and clearly demonstrates not only the complexity, but also the value of the pharmacist's role in the delivery of safe, accurate and appropriate supply of chemotherapy medicines to patients:

SAH Oncology Pharmacy Activity
Chemotherapy order (usually in Polymedic format) received by pharmacy. This follows diagnosis and appropriate chemotherapy regimen chosen by oncologist.
Pharmacist downloads and compares regimen against EVIQ standard to ensure all medications have been prescribed according to protocol and that there are no omissions etc.
Pre-treatment review by clinical pharmacist will confirm infusion dosages based on the body surface area, mode of delivery and that pre-treatment and discharge medications against recognised treatment regimen have been prescribed.
Pre-treatment interview with patient by oncology pharmacist. Potential medications can be identified and patient counselled about their cancer treatment and their pre and post treatment medicines.
Notwithstanding the pre-treatment review, the oncology pharmacist will review every dose of every patient prior to each cycle of chemotherapy to ensure that it is safe and clinically appropriate to proceed with treatment: weight, BSA, renal function, FBEs, LFTs and U&Es are reviewed and if required, changes made (or recommended to prescriber) to the doses of chemotherapy agent.
Once infusion doses are finalised, pharmacist prepares infusion order on the day prior to treatment. When compiled and checked it is faxed to the external compounder.
Where appropriate pre-med medications are supplied for each patient and delivered to the DIC on the day before treatment.
Chemotherapy infusions delivered at 7am the following day direct to the DIC. Oncology pharmacist receipts, unpacks and reconciles infusion order.
On the day of treatment the oncology pharmacist carries out a final check that the manufactured infusion has been correctly manufactured and labelled and ready for nurse administration. In addition, all fluids and associated medicines are dispensed and made ready for the patient.
Liaison with nursing staff who administer the medication to the patient
For all patients, the appropriate patient support pack and relevant information is provided to the patient. The pharmacist also takes this opportunity to assess any side-effects caused by the various treatments and ensures each patient has a sufficient supply of on-going associated medicines.
For new patients, the pharmacist will counsel the patient and provide consumer information to the patient regarding their medicines.
The patient receives the appropriate discharge medications to control symptoms such as nausea and vomiting and the pre-medications to be taken prior to the next cycle of chemotherapy.

Outsourcing the manufacture of chemotherapy infusions itself comes with additional administrative tasks, not encountered when supplying other non-chemotherapy infusion medications, or recognised as an essential medicine-related activity. Due to the lag time required to manufacture a batch of infusions off-site, the pharmacy team must carefully co-ordinate the correct infusion order the day prior to actual administration and only then issuing the medication on the day if the pre-ordered dose hasn't altered. A consequence of dose changes during this 'ordering/manufacturing window' or delayed use of an infusion (due to blood results etc.) with a short shelf life means that potentially high cost infusions are wasted.

2. Describe the professional and administrative practices for the provision of chemotherapy medicine infusions within the healthcare sector/s in which you participate and the business model/s which support them.

Chemotherapy Infusion Services at SAH are one element of a range of integrated cancer services. These cancer services maximise the ease and convenience of patient access to quality diagnostic and treatment services to influence survival and recovery outcomes. Easy and convenient access enables patients to continue to meet their family and work commitments, and helps maximise their psychosocial health.

The comprehensive range of facilities, services and expertise at Sydney Adventist Hospital which cancer patients utilise and benefit from includes:

- Over 800 qualified visiting accredited medical officers treating a broad range of conditions. These include but are not limited to general surgical, breast, urological, colorectal, gynaecological, and various medical, radiation, haematological and other Cancer specialists
- Diagnostic imaging - Mammogram, ultrasound, biopsy, interventional radiology, CT, MRI, X-Ray
- Nuclear Medicine (Northern Nuclear Medicine) including PET Scan
- Pathology
- Cancer Geneticist
- Day Infusion Centre
- Pre-Admission Clinic
- Specialist breast cancer nurse patient navigators
- Endoscopy/Day Surgery Facility/Operating Theatres/Recovery
- High Intensity Focused Ultrasound
- A da Vinci Surgical Robotic System
- Oncology Ward
- Radiation Oncology (Radiation Oncology Institute)
- Multidisciplinary specialist Doctor advisory teams
- Pharmacy
- Palliative Care
- Emergency Care
- Clinical Trials Unit
- Physiotherapy
- Speech Pathology
- Hospital in the Home program
- Nutrition and Dietetics
- Cancer Support Centre (counselling and support services)
- Carer's subsidised on site residential accommodation (Jacaranda Lodge)
- Oncology massage and complementary therapies
- Cancer Council Information Centre

Oncologists provide medical prescribing via nationally recognised cancer protocols aligned to the EVIQ standards. Specialist oncology-trained Pharmacists provide infusion/dispensing and counselling services, whilst specialised oncology and chemotherapy-accredited nurses administer infusions in the DIC.

This dedicated pharmacy oncology team is supported by a departmental business plan and management structure, which provides the professional and administrative functions to enable a chemotherapy service to be delivered. The specialised pharmacy team consists of a mix of oncology-trained pharmacists supported by technicians. Within SAH, the pharmacy is treated as a 'discrete business unit', operating as a 'business within a business'.

Situated in the private sector, all clinical activities undertaken by the pharmacy department have to be self-funded by the margins that are generated from the dispensing of PBS medicines. In the context of the SAH pharmacy oncology service, revenue generated must be sufficient to cover the cost of providing the chemotherapy medicines and of the clinical pharmacy service providing them.

As a not-for-profit organisation SAH has access to the PBS, and the cost of infusions/ chemotherapy operation is funded through the Efficient Funding of Chemotherapy Drugs (EFC) mechanism. It should be noted that this mechanism funds the supply of a PBS benefit alone and there is no element to reimburse the clinical service, which is intrinsically linked to the supply of that PBS benefit.

In financial terms, the current PBS funding contract underpinning the safe and accurate delivery of chemotherapy infusions is flawed in that it takes no account of the highly specialised processes and costs of preparing cancer drugs for infusion. In addition it does not adequately remunerate the range of clinical pharmacy services required to support the use of complex medicines, such as chemotherapy infusions, in hospitals.

The vast majority of patients treated at SAH will be covered by private health insurance and the patient's stay at SAH is determined by the terms and conditions negotiated between SAH and the health fund provider. As margins have been eroded over time with some infusions costing more than their PBS reimbursement, the question has been raised whether the health funds themselves would contribute to the 'gap'. The answer is an unequivocal no: health funds will not permit SAH to seek additional health fund recovery outside of existing contracts or contribute to any additional costs associated with the patient's episode of care. In addition, nor will they permit us to pass on the costs to our patients.

3. Can you identify and describe any changes to the provision of chemotherapy medicine infusion services over recent years? Have these changes (if relevant) affected consumer access to services and, if so, how?

Government-related Changes

Efficient Funding of Chemotherapy Drugs and the Price Disclosure Mechanisms

The continued preparation, dispensing and supply of chemotherapy medicines by SAH Pharmacy is now less viable as a result of successive and cumulative effects of funding changes. A shortfall in chemotherapy funding has come about through the Price Disclosure mechanism, which having gone through several cycles, has significantly reduced the price paid by Government for a number of off-patent chemotherapy

medicines, and a separate Budget measure (delayed until December 2011), that introduced a different funding model, the EFC, for chemotherapy infusions. In addition, Expanded and Accelerated Price Disclosure (EAPD) was introduced in 2010.

Chemotherapy Drugs Subject to Price Disclosure Reductions and Medicines Australia MOU

	Dec-09	Apr-10	Aug-10	Feb-11*	Apr-11	Aug-11	Apr-12	Aug-12	Dec-12	Total Reduction on original price	Approximate total annual reduction in government cost
DOXORUBICIN	-63.54%		-34.62%	-2.00%				-32.97%		-84.34%	\$ 20,505,664
MITOZANTRONE	-34.42%		-13.33%	-2.00%		-10.61%		-18.25%		-59.30%	\$ 368,723
CISPLATIN				-2.00%	-39.02%		-30.37%			-58.39%	\$ 2,890,044
GEMCITABINE				-2.00%	-37.00%		-53.65%			-71.38%	\$ 23,212,439
IRINOTECAN				-2.00%	-61.40%		-64.63%			-86.62%	\$ 24,111,421
PACLITAXEL				-2.00%	-52.58%					-53.53%	\$ 20,441,291
OXALIPLATIN				-2.00%		-72.54%		-51.76%		-87.02%	\$ 38,928,432
CARBOPLATIN*				-2.00%			-66.41%			-67.08%	\$ 9,962,596
EPIDUBICIN*				-2.00%			-78.05%			-78.49%	\$ 9,003,485
METHOTREXATE*				-2.00%			-20.20%			-21.80%	\$ 251,616
VINORELBINE				-2.00%			-63.87%			-64.59%	\$ 2,404,324
DOCETAXEL								-76.20%		-76.20%	\$ 41,531,627
ONDANSETRON* (injection)	-15.37%		-17.61%	-2.00%		-22.51%		-77.25%		-87.95%	\$ 436,964
											<u>\$ 194,048,626</u>

* Drugs brought into price disclosure as a result of Expanded & Accelerated Price Disclosure (EAPD)

* Mandatory reductions as a result of Medicines Australia MOU

* Ondansetron is not listed under the Efficient Funding of Chemotherapy program but is used for the management of nausea and vomiting in chemotherapy patients.

Ref: Community Pharmacy Chemotherapy Services Group. Patients to be Impacted by Cuts to Chemotherapy Drugs. 25-10-2012

On 1 December 2012, a 76.2% decrease in the PBS reimbursement for Docetaxel came into effect due to the cyclical Price Disclosure mechanism. Although media attention focused on docetaxel at this time, in reality, the trading terms on a number of drugs had already been gradually eroded over time, leaving only Docetaxel with no future opportunities to recoup funding. This was perceived by the industry as the tipping point and brought into question the sustainability of delivering a chemotherapy service without adequate funding. Whilst the PBS reimbursement price of many chemotherapy drugs has decreased, the cost of providing essential clinical pharmacy services to an increasing number of patients has not.

As described in the previous section, the SAH pharmacy business model has been reliant on the PBS-based EFC funding mechanism. Historically, SAH Pharmacy (as had the whole sector) had been utilising the revenue generated from a small number of non-patented drugs such as, but not limited to Docetaxel, to cross-subsidise or absorb the losses of other loss-making activities associated with the complex and costly compounding and supply of other chemotherapy-related medicines and clinical pharmacy services to patients.

Therefore, a combination of these two mechanisms, especially the on-going and cyclical nature of Price Disclosure driving down PBS remuneration, has removed the source of cross-subsidisation that underpinned the current business model. This has of course exposed the inadequacy of the previous remuneration arrangements. SAH acknowledges that this was done in good faith, ensuring continuity of treatment for the patient, continuing to achieve the best outcome for our patients and consistent with our mission ethos of 'Christianity In Action' – serving the needs of our community.

However, it is only as a result of this cross-subsidisation that SAH Pharmacy has been able to continue to supply those loss-making drugs. This is no longer the case. To date, these funding changes have not affected patient access to services, again consistent with our mission of *'Christianity In Action'*. However, the economic reality of the current EFC model is that it does not specifically and accurately reflect the individual costs associated with both the manufacture and the associated clinical skills required in the supply of chemotherapy medicines.

As there is no longer an income stream to maintain clinical pharmacy services associated with the supply of chemotherapy infusions, not only is the current business model unsustainable, but the cost of care and patient access will be affected. The negotiated dispensing fee of \$77 (as part of the December 2011 Chemotherapy Reforms) for the high level of skill required for the safe and professional dispensing of hazardous chemotherapy drugs is not adequate.

As a result of the ongoing changes and now with the additional latest December 1st funding reductions, Sydney Adventist Hospital estimates that the shortfall between fair and appropriate remuneration for supply and delivery at current service levels will be between of \$800,000 - \$1,000,000 by the end of the 2013 calendar year. Under PBS and Health Fund agreements, the Hospital is unable to pass onto patients this reduction in funding.

It also threatens the viability of an increase in patient chairs from 11 to 34, which is being planned in a new Day Infusion Centre as part of a new Integrated Cancer Centre currently under construction at Sydney Adventist Hospital. The increase was proposed to cater for increasing needs as the local population increases and ages.

San Day Infusion Centre has over 7,000 patient admissions each year of which approximately 5,000 relate to chemotherapy and oncology infusions. This includes over 40 public patients per month to whom SDIC provides chemotherapy services on behalf of the local public sector facility, the Hornsby Ku-ring-gai Hospital. If SAH cannot continue to provide their necessary infusions patients will be forced to find alternative private or public sector suppliers.

With Medicare and Health Fund agreements precluding any additional charges being levied on patients and therefore other private sector facilities facing the same viability issues as Sydney Adventist Hospital Pharmacy, other private sector choices may be limited for patients.

As the contracted provider for oncology infusions for public sector patients on behalf of the local Hornsby Ku-ring-gai public Hospital, SDIC will continue to meet its existing contractual commitments for the provision of services for public sector patients. Patients not able to be treated at San Day Infusion Centre or as inpatients may face delays in treatment, additional travel, and reduced choice for timely access, which will simply add to the distress of cancer patients dealing with the physical and emotional trauma of their illness.

Clinically-related Changes

Chemotherapy protocols are becoming more complex with an increase in multi-drug regimens. Consequently more time is required to clinically analyse the medication chart before ordering. These more complex protocols give rise to more side-effects and more complicated medication discharge plans. This then means that more time is needed to adequately advise and educate the patient. If staffing levels remain the same or decrease then the higher demand for time caused by these protocols cannot be met and best practice for patients cannot be achieved.

In recent years the introduction of monoclonal antibodies has added to the complexity of many protocols that previously were comprised of traditional chemotherapy only. Extra education and support is required for these patients as well as a higher level of clinical service to ensure optimum safety with regard to prevention of infusion reactions which are common with the monoclonals. The detrimental financial impact of providing monoclonal antibodies is discussed elsewhere in this document.

With the advent of oral chemotherapy there has been a rise in the number of IV/oral chemotherapy combination regimens. With such protocols there is an increase in the level of patient support required for side effects and explanation of discharge medications. The regimen may prove to be quite complicated and it is vital that each patient is educated sufficiently to ensure that the directions for the oral, discharge chemotherapy are understood. As this will be part of their treatment there could be an impact on outcomes if not adhered to correctly. Once again it is the amount of time needed for this level of support that is limited due to staff budget constraints.

Chemotherapy is also being given more routinely via infusion pumps and these require additional education and support. Furthermore these pumps have discrete doses with no provision for adjustment and also have a comparatively short shelf-life. Consequently wastage can often occur when patients are deferred or cancelled. The management of this in particular and chemotherapy wastage in general to protect the financial health of the pharmacy and the taxpayer requires significant input of staff time. Notwithstanding this the current PBS remuneration does not recognise the cost of supplying chemotherapy medication in a CADD or Surefusor device, which in some cases can be in excess of \$40.

The development of many new chemotherapy drugs, combination treatments and advancement in cancer care in general have all successfully led to better outcomes for patients and length of time to end-stage. This extended treatment time, multi-drug and multi-protocol exposure however can have an impact on the health of the patient. The consequence being that these patients, that are lasting longer in the cancer battle, are needing more and more support and assistance from pharmacists. This again impacts on the level of clinical involvement and places added strain on staff time to continue to provide optimum cancer care.

4. If third party compounders of chemotherapy medicines are used within your sector or institution please describe where and how they are incorporated within the practice and business model. Also discuss the reasoning for the decision to involve a third party compounder in preparing the chemotherapy infusions.

Due to the complexity of preparing chemotherapy infusions and the capital costs required to build, maintain and staff a compounding facility, a business decision was made about 3 years ago to out-source the manufacture of chemotherapy infusions. This decision to outsource was based upon a risk/benefit analysis of retaining an in-house facility to out-sourcing and consideration of TGA licensing requirements for manufacturing facilities.

SAH employs the services of one of the major national external compounders and has a good commercial and operational relationship with this company. The current business model for the supply of chemotherapy infusions is based upon the external third party compounder laterally integrated into pharmacy operations with the scripting process retained by SAH.

Due to the time required to manufacture chemotherapy infusions (complicated further by those infusions with short shelf lives), SAH pharmacy operations have to be very closely co-ordinated with the external compounder. A daily cut-off time is observed for the main order, which is delivered directly to the Day Infusion Centre early the following morning. This order is then checked by an oncology pharmacist to ensure the infusions have been correctly prepared.

As part of the original tender exercise, a 3-year contract was negotiated together with an agreed contract price list for a range of infusible chemotherapy medicines. This is typically a mixture of \$ per mg or vial price depending on the molecule. That said, compounding costs remains an external charge over which SAH Pharmacy has minimal control and in some cases PBS reimbursement does not always cover the cost of high external compounding costs. We recognise the third party providers also need to cover their costs and our external compounder has sharpened its prices as Price Disclosure has driven down the price paid for PBS drugs. However, invariably the price reduction offered by the compounder has not matched the percentage reduction in PBS remuneration.

5. Preparation and provision of chemotherapy medicine infusions undertaken by individual pharmacy businesses or business units within a larger institution. Describe the contractual or business arrangements in place with other upstream and/or downstream parts of the same healthcare sector.

The manufacture of all chemotherapy infusions are sourced from an external provider, therefore, this question does not apply.

6. Please describe the components of dispensing and clinical services provided in relation to infusible chemotherapy medicines? It may be useful to provide a comparison with dispensing practice for non-infusible medicines, such as tablets. Please consider the differences in relation to costs, time involved, skills required, outcomes achieved and activities undertaken?

For the purpose of this comparison, it is assumed the non-infusible medicine is an oral chemotherapy drug prescribed under PBS Authority, typically dispensed by a community pharmacist.

SAH Oncology Pharmacy Activity	Corresponding Pharmacy Activity for Non-infusible Medicines
Chemotherapy order (usually in Polymedic format) received by pharmacy. This follows diagnosis and appropriate chemotherapy regimen chosen by oncologist.	Prescription presented at pharmacy by patient. Confirms with whether patient wants generic substitution, patient's details and entitlements.
Pharmacist downloads and compares regimen against EVIQ standard to ensure all medications have been prescribed according to protocol and that there are no omissions.	Pharmacist checks that Authority details are correct and appropriate for supply.
Pre-treatment review by clinical pharmacist will confirm infusion dosages based on the body surface area, mode of delivery and that pre-treatment and discharge medications against recognised treatment regimen have been prescribed.	Check patient history on database when appropriate, interactions, allergies, dosage changes, medicine duplication prior to dispensing.
Pre-treatment interview with patient by oncology pharmacist. Potential medications can be identified and patient counselled about their cancer treatment and their pre and post treatment medicines.	No corresponding activity.
Notwithstanding the pre-treatment review, the oncology pharmacist reviews every dose of every patient prior to each cycle of chemotherapy to ensure that it is safe and clinically appropriate to proceed with treatment: weight, BSA, renal function, FBEs, LFTs and U&Es are reviewed and if required, changes made (or recommended to prescriber) to the doses of chemotherapy agent.	Checks for inappropriate drug therapy, contraindicated medicines, compliance problems, unusual dosage, and drug misuse or abuse. If necessary contact the prescriber and document any changes. Confirm doses and quantity of Schedule 8 medications if unfamiliar with prescriber.
Once infusion doses are finalised, pharmacist prepares infusion order on the day prior to treatment. When compiled and checked it is faxed to the external compounder.	Dispensing continues with drug selection and labelling as per Guide the Good Dispensing protocols.
Where appropriate pre-med medications are supplied for each patient and delivered to the DIC on the day before treatment.	No corresponding activity.
Chemotherapy infusions delivered at 7am the following day direct to the DIC. Oncology pharmacist receipts, unpacks and reconciles infusion order.	No corresponding activity.
On the day of treatment the oncology pharmacist carries out a final check that the manufactured infusion has been correctly manufactured and labelled and ready for nurse administration. In addition, all fluids and associated medicines are dispensed and made ready for the patient.	Pharmacist makes a final accuracy check of labelling, directions and drug selection.

Liaison with nursing staff who will administer the medication to the patient	No corresponding activity.
For all patients, the appropriate patient support pack and relevant information is provided to the patient. The pharmacist also takes this opportunity to assess any side-effects caused by the various treatments and ensures each patient has a sufficient supply of on-going associated medicines.	Any supportive material, for example, Consumer Medicines Information supplied. The pharmacist determines and provides the appropriate level of counselling.
For new patients, the pharmacist will counsel the patient and provide consumer information to the patient regarding their medicines.	New patients should be offered and counselled on the use of a new drug, if considered necessary by the pharmacist or if requested by the patient.
The patient receives the appropriate discharge medications to control symptoms such as nausea and vomiting and the pre-medications to be taken prior to the next cycle of chemotherapy.	No corresponding activity.

(Source: Adapted from SHPA Submission to Senate Committee, March 2013)

Although the same skills mix of pharmacist and technician staff are required in the oral dispensing process, tablet dispensing completely differs from “normal” or non-infusible chemotherapy treatments. The main difference is the absence of a compounding phase.

Costs: Less staff time is involved in dispensing oral tablets because an oral order does not have to be checked against protocols or prepared into an infusible container and checked by the oncology pharmacist. A disproportionate amount of pharmacist time is also spent with the patient during the various counselling phases inherent in supplying chemotherapy infusions compared to ‘normal’ counselling over the counter.

Skills: Oral chemotherapy tablets may be provided by another qualified pharmacist, but in practice the specialised counselling required by this cohort of patients usually requires a specialist oncology pharmacist to be involved.

Normal tablets/oral medication: core role of general pharmacist with no specialisation required, however, role still involves a degree of clinical check, accuracy, counselling and professional accountability, but not to the same extent as the dedicated oncology pharmacist.

7. Describe in detail one or more possible options for:

- The model of care for your institution (described in response to Q1);
- The professional practices for the provision of chemotherapy medicine infusions (described in response to Q2);
- Possible funding models for the preparation and supply of chemotherapy medicine infusions;
- The appropriate level and source of funding for each component of practice (described in response to Q6).

The model of care for your institution (described in response to Q1):

The current model of care is currently considered optimum to deliver the best clinical outcomes for our chemotherapy patients.

The professional practices for the provision of chemotherapy medicine infusions (described in response to Q2):

A sustainable funding model must replace the now compromised and inadequate cross-subsidisation business model. The model must be transparent across the industry and provide adequate PBS remuneration recognising:

- The cost of distribution from wholesalers.
- The costs associated with the compounding of chemotherapy infusion doses (or of compounding in-house).
- The costs of the pharmacy clinical services associated in the delivery of that PBS benefit.
- The costs of containers, consumables and dosage delivery services.

Sydney Adventist Hospital estimates that a fee increase of \$100 per infusion, which is consistent with that suggested by the industry bodies, will be required to ensure a sustainable model of supply for chemotherapy drugs.

Possible funding models for the preparation and supply of chemotherapy medicine infusions:

Sydney Adventist Hospital recognises the need to improve efficiency and manage the cost of the PBS and supports the underlying logic of Price Disclosure, which seeks to match the price of medicines provided by Government for chemotherapy medications with the market price or true price of these agents. We seek to be able to provide a quality, safe and effective service to our patients and community in a sustainable and transparent way considering all of the related costs.

That support is balanced, however, on the ability of the clinical pharmacy services to be adequately funded for the costs associated with the supply of chemotherapy medicines to patients. The professional services inherent in the safe and accurate supply of chemotherapy medicines to patients needs to be fully acknowledged and recognised and paid for in a transparent process that ensures that the costs of supply have been fully covered.

The funding model must acknowledge the complexity of providing treatment with chemotherapy and include reimbursement for the pharmacy service component. A more appropriate and transparent funding mechanism which includes reimbursement for the pharmacy service component is needed, removing the need for payment cross-subsidisation and addresses the assumption that the provision of a chemotherapy infusion service is only the purchase of a product.

SAH supports the following model as advocated by the SHPA which is a revised and transparent model that clearly identifies four component costs:

1. The cost of the chemotherapy medicine (payable for each medicine prepared) and the cost of all support medicines available through the PBS.
2. The cost of consumables and devices used in the preparation of each medicine and, if required by the chemotherapy protocol, the cost of the delivery device (payable for each medicine prepared).
3. A preparation and reconstitution fee (payable for each medicine prepared).
4. A pharmacy professional services fee/s covering:
 - a) The pre-treatment interview with the patient and pre-treatment clinical pharmacy review undertaken with other healthcare professionals involved in the patient's care (payable per chemotherapy course).
 - b) Clinical pharmacist review of each cycle of chemotherapy undertaken with other healthcare professionals involved in the patient's care (payable for each chemotherapy cycle).

(Source: SPHA Submission to Senate Committee, March 2013)

This model is predicated on the assumption that Government fully acknowledges and recognises the additional costs that are intrinsic in the delivery of chemotherapy infusions and as such do not have the same cost configuration as conventional medicines.

TERM OF REFERENCE 1E: COSTS AND COMPLEXITIES INVOLVED IN THE PROVISION OF CHEMOTHERAPY DRUGS

1. **Are there significant differences in the processes or costs of compounding certain infusible chemotherapy medicines? If so, please identify those medicines; describe the different practices or processes and evidence to support your position.**

SAH has identified a number of molecules whereby PBS remuneration either just, or does not cover the costs of manufacture let alone any associated clinical services required in their supply to a patient.

The Government announced an interim payment of \$60 per infusion 1 July to December 2013 and I have been able to update the financial data for the drugs that deliver little or no PBS return.

Prior to the July 2013 \$60.00 infusion rebate:

Drug	Number of Infusions per Year	Margin*
Rituximab	400	1.8%
Trastuzumab	360	1.2%
Bevacizumab	150	3.8%
Cetuximab	170	-11.7%
Natalizumab	200	-3.3%

Post July 2013 \$60.00 infusion rebate:

Drug	Number of Infusions per Year	Margin*
Rituximab	400	3.6%
Trastuzumab	360	3.1%
Bevacizumab	150	6.3%
Cetuximab	170	-8.2%
Natalizumab	200	-3.3%

*Please note that margins achieved on these medicines are solely the margins achieved net in store and takes no consideration of operational costs such as clinical staff, infrastructure and administrative costs.

It can be seen that across the spectrum of these agents that prior to July 2013, the returns on some drugs were very low and SAH were taking a loss on the supply of cetuximab (and natalizumab).

After July 2013, the increase of \$60 per infusion has slightly improved the margins of rituximab, trastuzumab and bevacizumab but cetuximab continues to cost more than the PBS remuneration model rebates SAH.

Two Infusion-related Issues:

1. Natalizumab: is used in the treatment of multiple sclerosis and is an integral part of the case-mix at SAH. Although not classified as a chemotherapy agent under EFC, as a monoclonal antibody it is **treated** as such and is subject to all the manufacturing, handling, storage and administration procedures as a chemotherapy agent. This means it undergoes exactly the same processes as a chemotherapy agent and requires external compounding. SAH has known for many years that this agent costs more than the PBS returns and has long relied on cross subsidisation from other agents to maintain its viability.
2. Cabazitaxel: a typical dose of 40mg will cost \$6,004.05 NIS with a PBS remuneration of \$6,022.40. This drug is still in advanced trials and although too early to comment, it seems that it is a successful agent in the treatment of prostate cancer. Currently, we only have a few patients on this agent, but if adopted as first line for prostate cancer in the future, this high-cost branded product will provide little return for a large capital output, again without contributing to any associated clinical services costs required in its supply to a patient. In addition, any arbitrary increase in mark-up by the external compounder would have a similar financial effect to that currently being experienced with cetuximab.

2. If you described a different practice for certain infusible chemotherapy medicines (in response to Q1) should these be managed or funded differently to other chemotherapy medicines? If so, please describe a possible alternative funding model for these medicines.

The PBS list price (ex-manufacturer cost price) is not always the price that is charged by our external compounder. In some instances the cost price of the medicine, either in \$ per mg or per vial is significantly higher than the PBS listed cost price.

Consequently, there should be more engagement with the pharmaceutical industry to ensure that the centrally negotiated ex-manufacturer price is more attuned and realistic with market forces.

This would then entail regulation of chemotherapy compounding sector prices to ensure PBS remuneration model more accurately reflects the actual market and manufacturing costs of chemotherapy infusions into store.

TERM OF REFERENCE 3: QUALITY OF INFUSION PREPARATIONS

1. What are the range of relevant guidelines and standards that apply to chemotherapy services across States and Territories? How are these standards enforced – i.e. regulations, on-site audits? Which if any of these standards should apply where drugs are being compounded on-site, or purchased from a third party, or prepared days before the infusion is delivered? How are adverse events monitored and reported?

a. What are the range of relevant guidelines and standards that apply to chemotherapy services across States and Territories?

- TGA good manufacturing practice.
- SHPA Oncology Guidelines.
- Cold chain.
- ACSQHC Standards, mandatory January 2013, specifically Medication Safety, Standard 4.

b. How are these standards enforced – i.e. regulations, on-site audits?

- ACSQHC Standards: ISO certification – on-site inspection.
- On site TGA certification of compounding premises.
- Quality KPIs written into SAH contract.
- Stability of product/shelf-life of products.

c. Which if any of these standards should apply where drugs are being compounded on-site, or purchased from a third party, or prepared days before the infusion is delivered?

- For SAH who purchases from a third party compounder – all standards apply.

d. How are adverse events monitored and reported?

- KPIs written into SAH contract.
- Stock monitored at receipting stage by Oncology Pharmacist and faults reported direct to compounder.
- Intervention recorded in organisation's risk management program – RISKMAN. Incidents trended and reported to monthly DTC.
- ADRAC on-line.

All private hospitals are required to meet the requirements of The National Standards for safety and Quality in Health Facilities together with State private hospitals licensing requirements and legislation regarding workplace health and safety, poisons regulations, waste disposal and building. The ACSQHC is currently conducting a project to identify areas of overlap and duplications in these arrangements.

Guidelines outlined by the Society of Hospital Pharmacists Australia guide practice in private hospitals and day clinics providing chemotherapy. Health Funds frequently specify their own quality requirements as a contract condition.

In addition third party compounders are required to meet the requirements of the TGA.

2. Is further development of current standards required? If so, in which area is work needed? Is there other work, such as the development of quality programs, required? How can consumers be involved in the development of standards and programs to ensure quality services?

The National Standards include both core and developmental actions. Health facilities are required to achieve accreditation against core actions and over time they will be required to achieve accreditation against developmental standards. Consumer engagement (standard 2) is integral to the National Standards as a whole.

a. Is further development of current standards required?

- The current standards are adequate.
- The compounder's compliance with current standards adds to the cost of goods-into-store costs.

b. If so, in which area is work needed?

- As above.

c. Is there other work, such as the development of quality programs, required?

- SAH quality programs continue to progressively develop.
- Additional standards add to drug costs.

d. How can consumers be involved in the development of standards and programs to ensure quality services?

- SAH customer service surveys.
- Clinical focus groups.

The National Standards include both core and developmental actions. Health facilities are required to achieve accreditation against core actions and over time they will be required to achieve accreditation against developmental standards. Consumer engagement (standard 2) is integral to the National Standards as a whole.

3. Should meeting any of these standards be a mandatory requirement for Commonwealth funding? If so, which? How would this be managed or enforced? Are there different standards that should be met depending on the circumstances under which the infusion is prepared? What would the effect of any changes be for consumers, in terms of access to and quality of chemotherapy services?

a. Should meeting any of these standards be a mandatory requirement for Commonwealth funding?

- Yes TGA standards.
- ACSQHC Standards.

b. If so, which?

- TGA standards.
- ACSQHC Standards.

c. How would this be managed or enforced?

d. Are there different standards that should be met depending on the circumstances under which the infusion is prepared?

- Cold chain for refrigerated products.

e. What would the effect of any changes be for consumers, in terms of access to and quality of chemotherapy services?

TERM OF REFERENCE 3: OTHER MATTERS PERTINENT TO FUNDING FOR CHEMOTHERAPY INFUSION PREPARATION

PBS requirements for drug authorities and paper based prescriptions and claiming contribute significantly to the administrative workload associated with the provision of chemotherapy services. The administrative burden of supplying chemotherapy agents through the PBS is substantial.

Introduction of paperless claim as per Residential Home paperless system would significantly streamline this process. Implementation of online prescribing and claiming has been trialled over many years in selected facilities. The results of this trial should be evaluated and published as soon as possible to inform future policy.

PBS requirements for drug authorities and paper based prescriptions and claiming should be removed to improve administrative efficiency and improve quality and safety through reduction in medication error and improved management and communication of clinical information across the clinical pathway. Modernisation is required!

While promising significant efficiencies, further roll-out of online prescribing and claiming will require sufficient time for the careful planning, system design and change management required to ensure success. Government assistance will be required to

enable pharmacy services to implement such systems as one strategy in ensuring the viability of private chemotherapy services.

Price Disclosure: DoHA calculations include prices paid for drugs, which are supplied through third party compounders to the public health system. This was not the intention and results in the PBS reimbursement prices being pushed lower than the private market place. This should be reviewed to avoid on-going pricing being distorted by public sector purchases through external compounders.

EFC algorithm: the algorithm used for the calculation of PBS reimbursement amounts was not implemented as expected based on DoHA advice to the key stakeholder groups prior to the implementation of the changes. Nor was it trialled! This should be reviewed to ensure the maximum level of reimbursement is obtainable.